PART VI
USE OF THERAPEUTIC EQUIPMENT

RHB 6.1 Scope. This part establishes requirements for use of therapeutic equipment by persons licensed to practice one or more of the health professions within the authority granted to them by statute or regulation. Therapeutic equipment in this part will be defined as any therapeutic machine capable of producing a useful beam of x-rays, or x-rays and charged particles with energies greater than 500 keV. Particle accelerators meeting this definition will be regulated under this part while all other particle accelerators will be regulated under Title C. The provisions of this part are in addition to, and not in substitution for, other applicable provisions of these regulations. All provisions of this Part apply to therapeutic veterinary installations.

RHB 6.2 Shielding Requirements for all Therapeutic X-ray Equipment.

6.2.1 Each installation shall be provided with protective barriers as are necessary to assure compliance with RHB 3.3, RHB 3.4 and RHB 3.6. The requirement shall be deemed met if the thickness of such barriers is equivalent to the thickness as computed in accordance with calculations in the National Council on Radiation Protection and Measurements (NCRP) Report #51, "Radiation Protection Design Guidelines for .1-100 MeV Particle Accelerator Facilities", NCRP Report #49 "Structural Shielding Design and Evaluation for Medical Use of X-rays and Gamma Rays of Energies up to 10 MeV", or an equivalent reference.

6.2.2 Shielding. Prior to construction, the floor plans and equipment arrangement of all new installations, or modifications of existing installations, utilizing ionizing radiation for therapeutic purposes shall be reviewed by a Class VII vendor and submitted to the Department for review and approval. The registrant shall submit plans and a report, including any recommendations and all basic assumptions used, from the vendor to the Department. The approval of such plans shall not preclude the requirement of additional modifications should a subsequent analysis of operating conditions indicate the possibility of an individual receiving a dose in excess of the limits prescribed in Part III of these regulations.

6.2.3 After installation of a radiation machine, the facility shall maintain for inspection by the Department:

6.2.3.1 The maximum rating of technique factors;

6.2.3.2 A scale drawing of the room in which a stationary radiation machine system is located with such drawing indicating the use of areas adjacent to the room and an estimation of the extent of occupancy by an individual in such areas. In addition, the drawing shall include:

6.2.3.2.1 The results of a survey for radiation levels present at the operator's position and at pertinent points outside the room at specified test conditions, or

6.2.3.2.2 The type and thickness of materials, or lead equivalency, of each protective barrier.

6.2.4 After construction and installation are complete, the registrant shall submit "as built" drawings to the Department for review. These drawings shall indicate the composition of all walls and the placement of the x-ray equipment and control. "As built" drawings may be submitted after shielding installation is complete while cosmetic finishing continues.

6.2.5 The therapeutic x-ray equipment shall not be used before a shielding plan for the unit has been approved by the Department, and "as built" drawings have been submitted.

RHB 6.3 General Provisions for All Therapeutic Equipment.

6.3.1 Radiation Safety Officer.

6.3.1.1 The registrant shall designate an individual who will be responsible for radiation protection for the therapeutic equipment. Such individual may be a radiological physicist, and shall:

6.3.1.1.1 Be qualified by training and experience concerning all hazards and precautions involved in operating the therapeutic equipment for which he is responsible.

6.3.1.1.2 Recommend a detailed program of radiation safety for effective compliance with the applicable requirements of these regulations.

6.3.1.1.3 Give instructions concerning hazards and safety practices to individuals who may be exposed to radiation from the therapeutic equipment.

6.3.1.1.4 Make surveys and carry out other procedures as required by these regulations.

6.3.1.2 Each therapeutic machine shall be under the administrative control of a radiological physicist who will be responsible for the safe operation of the equipment.

6.3.2 Procedures.

6.3.2.1 Written operating procedures as well as specified safety rules shall be established for each therapeutic unit facility and approved by the radiation safety officer.

6.3.2.1.1 Operating procedures. The written operating procedures to be implemented shall include the following:

6.3.2.1.1.1 The accelerator is used in such a manner that patients, workers, and the general public are protected from radiation hazards and the provisions of Part III of these regulations are met;

6.3.2.1.1.2 No therapeutic machine shall be left unattended unless it is secured against unauthorized use;

6.3.2.1.1.3 The safety interlock system shall not be used to terminate the exposure except in an emergency;

6.3.2.1.1.4 If a patient needs support or restraint during therapy, mechanical supporting or restraining devices shall be used;

6.3.2.1.1.5 No individual other than the patient shall be in the therapy room during irradiation;

6.3.2.1.1.6 Startup procedures for the accelerator, specified by the therapeutic radiological physicist, shall be performed daily prior to treatment of patients;

6.3.2.1.1.7 The accelerator shall not be used for treatment of patients unless the operator can maintain visual observation of the patient and audible communication with the patient; and

6.3.2.1.1.8 Policies and procedures for pregnant workers; NRC Regulatory Guide 8.13, "Instruction Concerning Prenatal Radiation Exposure" should be used for guidance concerning pregnant workers;

6.3.2.1.1.9 Policies and procedures for personnel monitoring;

6.3.2.1.1.10 Policies and procedures for training new employees; and

6.3.2.1.1.11 Policies and procedures for identifying and reporting misadministrations, as defined by RHB 8.120.

6.3.2.1.1.12 Policies and procedures for quality assurance. In addition to other quality assurance and quality control procedures required at a therapy facility, the facility must have a policy and procedure which specifically addresses annual equipment performance testing on radiation therapy simulators and CT scanners used for treatment planning. This policy and procedure must address standards for film processing, which includes processor quality assurance, evaluation of darkroom conditions and film, periodic inspection and cleaning of film cassettes and screens, view box lighting conditions, and periodic testing of safety interlocks and warning systems.

6.3.2.1.2 Emergency Procedures. The emergency procedures shall include:

6.3.2.1.2.1 Instructions for alternate methods for termination of irradiation and machine movements.

6.3.2.1.2.2 Instructions for contacting the therapeutic radiological physicist when operational problems or emergencies occur and the actions that are to be taken until the physicist can be contacted.

6.3.2.2 Operators and maintenance personnel shall be familiar with and have available a copy of the written operating and emergency procedures. Documentation must be maintained indicating that the operator or maintenance person has read and agrees to adhere to the operating procedures.

6.3.3 Operator Requirements and Training.

6.3.3.1 The registrant shall assure that all therapeutic equipment under his control is operated only by a radiation therapist possessing a current, valid certificate from the South Carolina Quality Standards Association, or a licensed practitioner. For the purpose of this Part, a radiation therapist is defined as a person who applies radiation to humans for therapeutic purposes; performs treatment setups, including, but not limited to, patient positioning, setting of treatment parameters on the control panel, and verification of treatment accessories; or documents daily treatments for a patient's chart.

6.3.3.2 In-house modification, repairs, or preventative maintenance on therapeutic equipment components or safety interlocks may be performed only by or under the direct supervision of persons who have received at least the minimum training specified in RHB 6.3.3.12 and demonstrated competence specified in RHB 6.3.3.13.

6.3.3.3 No person other than a licensed practitioner or a radiation therapist possessing a current, valid certificate from the South Carolina Quality Standards Association shall use equipment emitting ionizing radiation on humans for therapeutic purposes.

6.3.3.4 No person shall employ or designate as a radiation therapist a person who does not hold a certificate issued by the South Carolina Quality Standards Association.

6.3.3.5 No person holding a certificate issued by the South Carolina Quality Standards Association shall use equipment emitting ionizing radiation on humans for therapeutic purposes unless under the direction and supervision of a licensed practitioner and unless so directed by prescription of a licensed practitioner.

6.3.3.6 No person who is not certified by the South Carolina Quality Standards Association shall take, use, or exhibit the title of "limited practice radiographer," "radiographer," or "radiation therapist" or any other title, sign, display, or declaration that tends to lead the public to believe that the person is authorized to apply ionizing radiation on humans for therapeutic purposes.

6.3.3.7 A student enrolled in and attending a school or college of medicine, radiologic technology, radiation therapy, or a curriculum approved by the South Carolina Quality Standards Association, or a resident in an approved graduate education program of medicine may apply ionizing radiation to humans without a certificate from the South Carolina Quality Standards Association as long as the student or resident is under the supervision of a licensed practitioner or direct supervision of a certified radiation therapist appropriately trained to supervise the specific procedure.

6.3.3.8 The registrant shall display each operator's current certificate in public view, not obstructed by any barrier, equipment, or other object.

6.3.3.9 The registrant shall ensure that each operator has received training specific to the equipment and procedures in use at his facility, including machine specific training, use of personnel monitoring devices, quality assurance procedures, and the operating procedures required by RHB 6.3.2.

6.3.3.10 All operators shall receive at least one month of on the job training before assuming operational responsibility.

6.3.3.11 The registrant shall maintain a record of all training for each operator. Such records shall be made available for Departmental inspection.

6.3.3.12 Training of in-house and test maintenance personnel shall include:

6.3.3.12.1 Fundamentals of Radiation Safety;

6.3.3.12.1.1 Characteristics of radiation.

6.3.3.12.1.2 Units of radiation dose.

6.3.3.12.1.3 Hazards of excessive exposure to radiation.

6.3.3.12.1.4 Levels of radiation from therapeutic equipment.

6.3.3.12.1.5 Methods used to prevent radiation exposure including shielding, interlocks, safety rules, and radiation monitoring equipment.

6.3.3.12.2 Use and care of personnel monitoring equipment employed at the facility.

6.3.3.12.3 Location and use of all operating controls.

6.3.3.12.4 Requirements of pertinent State Regulations.

6.3.3.12.5 Registrant's written operating and emergency procedures.

6.3.3.13 In-house personnel who are to perform or directly supervise modifications, tests or maintenance work shall demonstrate the following capabilities to the radiation safety officer:

6.3.3.13.1 Ability to read and understand electrical diagrams.

6.3.3.13.2 A thorough knowledge of the principles and operation of the therapeutic equipment.

6.3.3.13.3 A thorough knowledge of the safety interlock system.

6.3.3.13.4 Ability to understand, use, and check the operation of radiation survey instruments.

6.3.3.14 The registrant shall maintain a record of all training for in-house testing and maintenance personnel. Such records shall be made available for Departmental inspection.

6.3.4 Control.

6.3.4.1 The radiation safety officer shall maintain a current list of all personnel who are qualified to service the therapeutic equipment.

6.3.4.2 No registrant shall permit a therapeutic unit to operate at any time with a safety interlock bypassed, except for necessary testing.

6.3.5 Technique indicators. Instrumentation readouts and controls on the therapy control console must be clearly identified and easily discernable.

RHB 6.4 Therapeutic X-ray Systems of Less than 1 MeV.

6.4.1 Equipment requirements.

6.4.2 Leakage radiation. When the tube is operated at its leakage technique factors, the leakage radiation shall not exceed the values specified at the distance stated for the classification of that x-ray system shown in Table 1.

TABLE 1. LEAKAGE LIMITS FOR THERAPEUTIC X-RAY SYSTEMS OF LESS THAN 1 MeV.

System	Leakage Limit	Measurement Location
Contact Therapy	100 mR/hr	5 cm from surface of tube housing
0-150 kVp (manufactured source or installed prior to the effective date of these regulations)	1 R in 1 hr.	1 m from
0-150 kVp (manufactured on or after the effective date of these regulations)	100 mR in 1 hr	1 m from source
151-500 kVp	1 R in 1 hr	1 m from source
500-999 kVp	0.1 percent of source useful beam or 1 R in 1 hr.	1 m from

6.4.1.2 Permanent Beam-Limiting Devices. Permanent fixed diaphragms or cones used for limiting the useful beam shall provide the same or a higher degree of protection as required for the tube housing assembly.

6.4.1.3 Removable and Adjustable Beam-Limiting Device.

6.4.1.3.1 Removable beam-limiting devices shall, for the portion of the useful beam to be blocked by these devices, transmit not more than 1 percent of the useful beam at the maximum kV and maximum treatment filter. This requirement does not apply to auxiliary blocks or materials placed in the useful beam to shape the useful beam to the individual patient.

6.4.1.3.2 Adjustable beam-limiting devices shall, for the portion of the x-ray beam to be blocked by these devices, transmit not more than 5 percent of the useful beam at the maximum kV and maximum treatment filter.

6.4.1.3.3 Adjustable beam-limiting devices installed after the effective date of these regulations shall meet the requirements of 6.4.1.3.

6.4.1.4 The filter system shall be so designed that:

5.6.4.1.4.1 The filters cannot be accidentally displaced at any possible tube orientation;

6.4.1.4.2 For equipment installed after the effective date of these regulations, an interlock system prevents irradiation if the proper filter is not in place;

6.4.1.4.3 The radiation at 5 centimeters from the filter insertion slot opening does not exceed 30 Roentgens (7.74 mC/kg) per hour under any operating conditions; and

6.4.1.4.4 Each filter is marked as to its material of construction and its thickness. For wedge filters, the wedge angle shall appear on the wedge or wedge tray.

6.4.1.5. Tube Immobilization. The tube housing assembly shall be capable of being immobilized for stationary treatments.

6.4.1.6 Focal Spot Marking. The tube housing assembly shall be so marked that it is possible to determine the location of the focal spot to within 5 millimeters, and such markings shall be readily accessible for use during calibration procedures.

6.4.1.7 Beam Block. Contact therapy tube housing assemblies shall have a removable shield of at least 0.5 millimeter lead equivalency at 100 kVp that can be positioned over the entire useful beam exit port during periods when the beam is not in use.

6.4.1.8 Beam Monitor System. Systems of greater than 150 kVp manufactured after the effective date of these regulations shall be provided with a beam monitor system which:

6.4.1.8.1 Shall have the detector of the monitor system interlocked to prevent incorrect positioning;

6.4.1.8.2 Shall not allow irradiation until a preselected value of exposure has been made at the treatment control panel;

6.4.1.8.3 Shall independently terminate irradiation when the preselected exposure has been reached;

6.4.1.8.4 Shall be so designed that, in the event of a system malfunction or electrical power failure, the dose administered to a patient prior to the system malfunction or power failure can be accurately determined;

6.4.1.8.5 Shall have a display at the control panel from which the dose at a reference point in soft tissue can be calculated;

6.4.1.8.6 Shall have a control panel display which maintains the administered dose reading until intentionally reset to zero; and

6.4.1.8.7 Shall have a control panel display which does not have scale multiplying factors and utilizes a design such that increasing dose is displayed by increasing numbers.

6.4.1.9 Timer.

6.4.1.9.1 A timer which has a display shall be provided at the treatment control panel. The timer shall have a preset time selector.

6.4.1.9.2 The timer shall activate with the production of radiation and retain its reading after irradiation is interrupted. After irradiation is terminated and before irradiation can be reinitiated, it shall be necessary to reset the elapsed time indicator to zero.

6.4.1.9.3 The timer shall terminate irradiation when a preselected time has elapsed, if any dose monitoring system present has not previously terminated irradiation.

6.4.1.9.4 The timer shall permit accurate presetting and determination of exposure times as short as 1 second.

6.4.1.9.5 The timer shall not permit an exposure if set at zero.

6.4.1.9.6 The timer shall not activate until the shutter is opened when irradiation is controlled by a shutter mechanism unless calibration includes a timer factor to compensate for mechanical lag.

6.4.1.9.7 Timers shall be accurate to within 1 percent of the selected value or 1 second, whichever is greater.

6.4.1.10. Control Panel Functions. Within one year of the effective date of these regulations, the control panel, in addition to the displays required in other provisions of this Part shall have:

6.4.1.10.1 An indication of whether electrical power is available at the control panel and if activation of the x-ray tube is possible;

6.4.1.10.2 An indication of whether x-rays are being produced;

6.4.1.10.3 Means for indicating x-ray tube potential and current;

6.4.1.10.4 Means for terminating an exposure at any time

6.4.1.10.5 A locking device which will prevent unauthorized use of the x-ray system; and

6.4.1.10.6 For x-ray systems manufactured after the effective date of these regulations, a positive display of specific filters in the beam.

6.4.1.11 Multiple Tubes. When a control panel may energize more than one x-ray tube:

6.4.1.11.1 It shall be possible to activate only one x-ray tube at any time;

6.4.1.11.2 There shall be an indication at the control panel identifying which x-ray tube is activated; and

6.4.1.11.3 There shall be an indication at the tube housing assembly when that tube is energized.

6.4.1.12 Source to Skin Distance (SSD). There shall be means of determining initially the SSD to within 1 centimeter and of producing this measurement to within 2 millimeters thereafter.

6.4.1.13 Shutters. Unless it is possible to bring the x-ray output to the prescribed exposure parameters within 5 seconds, the beam shall be attenuated by a shutter having a lead equivalency not less than that of the tube housing assembly.

6.4.1.13.1 After the unit is at operating parameters, the shutter shall be controlled electrically by the operator from the control panel.

6.4.1.13.2 An indication of shutter position shall appear on the control panel.

6.4.2 Facility Design Requirements for Therapy X-ray Systems Capable of Operating Above 50 kVp.

6.4.2.1 Aural Communication. Provision shall be made for two-way aural communication between the patient and the operator at the control panel. However, where excessive noise levels or treatment requirements make aural communication impractical, other methods of communication shall be used.

6.4.2.2 Viewing Systems.

6.4.2.2.1 Windows, mirrors, closed circuit television, or an equivalent system shall be provided to permit continuous observation of the patient during irradiation and shall be so located that the operator can observe the patient from the control panel.

6.4.2.2.2 When the primary viewing system is by electronic means, an alternate viewing system, which may be electronic, shall be available for use in the event of failure of the primary viewing system.

6.4.2.2.3 Should both systems described in 6.4.2.2.2 above fail or be inoperative, treatment shall not be performed with the unit until one of the systems is restored.

6.4.2.3 Barriers. With equipment operating at voltages above fifty (50) kVp, the required barriers shall be an integral part of the building.

6.4.2.4 Multiple Access. Treatment rooms to which access is possible through more than one entrance shall be provided with flashing warning lights in a readily observable position near the outside of all access doors, which will indicate when the useful beam is "on". Interlocks shall be provided such that all entrance doors must be closed, including doors to any interior booths, before treatment can be initiated or continued. If the radiation beam is interrupted by any door opening, it shall not be possible to restore the machine to operation without closing the door and reinitiating irradiation by manual action at the control panel.

6.4.3 Additional Requirements for X-ray Systems Capable of Operating Above 150 kVp.

6.4.3.1 All protective barriers shall be fixed except for entrance doors or beam interceptors.

6.4.3.2 The control panel shall be within a protective booth equipped with an interlocked door or located outside the treatment room or in a totally enclosed booth, which has a ceiling, inside the room.

6.4.3.3 Interlocks shall be provided such that all entrance doors must be closed, including doors to any interior booths, before treatment can be initiated or continued. If the radiation beam is interrupted by any door opening, it shall not be possible to restore the machine to operation without closing the door and reinitiating irradiation by manual action at the control panel.

6.4.3.4 When any door referred to in6.4.3.3 is opened while the x-ray tube is activated, the exposure at a distance of 1 meter from the source shall be reduced to less than 100 milliroentgen per hour.

6.4.3.5 A scram button or other emergency power cut-off switch shall be located and easily identifiable in all accessible high radiation areas.

6.4.3.6 All safety and warning devices, including interlocks, shall be tested and appropriately serviced after each 500 hours of operation or at intervals not to exceed six months, whichever comes first. Documentation shall be kept and available for review of all testing and servicing.

6.4.4 Surveys, Calibrations, and Spot Checks.

6.4.4.1 Surveys.

6.4.4.1.1 All new facilities, and existing facilities not previously surveyed shall have a survey made by or under the direction of a qualified expert who is authorized by the Department to perform such surveys. Such surveys shall be done after any change in the facility or equipment which might cause a significant increase in radiation hazard. A record shall be made of the therapeutic operating conditions and radiation levels measured at specific control points. One of these control points must be at the normal work station of the operator.

6.4.4.1.2 The registrant shall obtain a written report of the survey from the qualified expert. A copy of the initial report shall be transmitted by the registrant to the Department within 30 days of the first patient treatment following the survey. The registrant shall maintain all subsequent reports for inspection by the Department.

6.4.4.1.3 The survey and report shall indicate all instances where the installation, in the opinion of the qualified expert, is in violation of applicable rules or regulations.

6.4.4.1.4 The registrant shall maintain sufficient calibrated and operable radiation survey instruments to make physical radiation surveys as required by this part of these regulations. Each radiation survey instrument shall be response checked every three months and calibrated once a year. After each instrument servicing, a record shall be maintained of the latest response check or calibration date.

6.4.4.2 Calibrations. Calibrations of x-ray systems subject to the requirements of this Part shall meet the following requirements:

6.4.4.2.1 The calibration of an x-ray system shall be performed at intervals not to exceed 1 year and after any change or replacement of components which could cause a change in the radiation output on output.

6.4.4.2.2 The calibration of the radiation output of the x-ray system shall be performed by or under the direction of a radiological physicist who is physically present at the facility during such calibration.

6.4.4.2.3 Calibration of the radiation output of an x-ray system shall be performed with a calibrated dosimetry system. The calibration of such system shall be traceable to a national standard. The system shall have been calibrated within the preceding two years.

6.4.4.2.4 The calibration shall be such that the dose at a reference point in a water or tissue equivalent phantom can be calculated to within an uncertainty of 5 percent. For superficial units, free-in-air calibrations are acceptable.

6.4.4.2.5 The calibration of the x-ray system shall include, but not be limited to, the following determinations:

6.4.4.2.5.1 Verification that the x-ray system is operating in compliance with the design specifications;

6.4.4.2.5.2 Half-value layer for each kV setting and filter combination used;

6.4.4.2.5.3 The exposure rates as a function of field size, technique factors, filter, and treatment distance used; and

6.4.4.2.5.4 The degree of congruence between the radiation field and the field indicated by the localizing device if such device is present which shall be within 5 millimeters for any field edge.

6.4.4.2.6 Records of calibrations shall be maintained by the registrant for 5 years after completion of the calibration. The records shall be available for review.

6.4.4.2.7 A copy of the most recent x-ray system calibration shall be available at or in the general area of the control panel.

6.4.4.2.8 A copy of the most recent x-ray system calibration shall be submitted to the Department upon request.

6.4.4.3 Spot Checks. Spot checks shall be performed on x-ray systems capable of operation at greater than 150 kVp. Such spot checks shall meet the following requirements:

6.4.4.3.1 The spot check procedures shall be in writing and shall have been developed by a radiological physicist. A copy of the procedures shall be submitted to the Department upon request.

6.4.4.3.2 If the radiological physicist does not perform the spot check measurement, the results of the spot check measurements shall be reviewed by the radiological physicist within 7 treatment days and a record made of the review.

6.4.4.3.3 The spot check procedures shall specify the frequency at which tests or measurements are to be performed. The spot check procedures shall specify that the spot check shall be performed during the calibration specified in 6.4.4.2. The acceptable tolerance for each parameter measured in the spot check when compared to the value for that parameter determined in the calibration specified in 6.4.4.2 shall be stated.

6.4.4.3.4 The written spot check procedures shall include special operating instructions which shall be carried out whenever a parameter in 6.4.4.2 exceeds an acceptable tolerance.

6.4.4.3.5 Whenever a spot check indicates a significant change in the operating characteristics of a system, as specified in the spot check procedures, the system shall be recalibrated, as required in 6.4.4.2.

6.4.4.3.6 Records of spot check measurements and any necessary corrective actions shall be maintained by the registrant for 2 years after completion of the spot check measurements. A copy of the most recent spot check shall be available at or in the area of the control panel.

6.4.4.3.7 Where a spot check involves a radiation measurement, such measurement shall be obtained using a system satisfying the requirements of 6.4.4.2.3 or which has been intercompared with a system meeting those requirements within the previous year.

6.4.4.4 Prohibited use. The x-ray system shall not be used in the administration of radiation therapy unless the requirements of 6.4.4.2 and 6.4.4.3 have been met.

RHB 6.5 X-ray and Electron Therapy Systems with Energies of 1 MeV and Above. These rules shall apply to facilities using therapy systems with energies 1 MeV and above. The records shall be maintained and available for review.

6.5.1 Leakage Radiation to the Patient Area. Equipment shall meet the following requirements:

6.5.1.1 For operating conditions producing maximum leakage radiation, the absorbed dose in rads (Grays) due to leakage radiation, including x-rays and electrons, at any point in a circular plane of 2 meters radius centered on and perpendicular to the central axis of the beam at the isocenter or normal treatment distance and outside the maximum useful beam size shall not exceed 0.1 percent of the maximum absorbed dose in rads (Grays) of the unattenuated useful beam measured at the point of intersection of the central axis of the beam and plane surface. Measurements excluding those for neutrons shall be averaged over an area up to, but not exceeding, 100 square centimeters at the positions specified. Measurements of the portion of the leakage radiation dose contributed by neutrons shall be averaged over an area up to, but not exceeding, 200 square centimeters.

6.5.1.2 For each system, the registrant shall determine or obtain from the manufacturer the leakage radiation existing at the positions specified in 6.5.1.1 for the specified operating conditions. Records on leakage radiation measurements shall be maintained for inspection by the Department.

6.5.2 Beam-Limiting Devices. Adjustable or interchangeable beam limiting devices shall be provided and such devices shall transmit no more than 2 percent of the useful photon beam at the normal treatment distance for the portion of the useful beam which is to be attenuated by the beam-limiting device. The neutron component of the useful beam shall not be included in this requirement.

6.5.3 Filters.

6.5.3.1 Each filter which is removable from the system shall be clearly marked with an identification number. Documentation available at the control panel shall contain a description of the filter. For wedge filters, the wedge angle shall appear on the wedge or wedge tray (if permanently mounted to the tray). If the wedge tray is damaged, the wedge transmission factor shall be redetermined.

6.5.3.2 If the absorbed dose rate data required by 6.5.15 relates exclusively to operation with a field-flattening filter or beam scattering foil in place, such filter shall be removable only by the use of tools.

6.5.3.3 For equipment installed after the effective date of these regulations, which utilizes a system of wedge filters, interchangeable field-flattening filters, or interchangeable beam scattering foils:

6.5.3.3.1 Irradiation shall not be possible until a selection of a filter or a positive selection to use "no filter" has been made at the treatment control panel, either manually or automatically.

6.5.3.3.2 An interlock system shall be provided to prevent irradiation if the filter selected is not in the correct position.

6.5.3.3.3 A display shall be provided at the treatment control panel showing filters in use.

6.5.3.3.4 An interlock shall be provided to prevent irradiation if any filter selection operation carried out in the treatment room does not agree with the filter selection operation carried out at the treatment control panel.

6.5.3.4 Attenuation of wedges and compensator devices must be checked before the device is placed into service. A visual inspection of the mechanical integrity of these accessories must be done monthly.

6.5.4 Beam Quality. The registrant shall determine data sufficient to assure that the following beam quality requirements in tissue equivalent material are met:

6.5.4.1 The absorbed dose resulting from x-rays in a useful electron beam at a point on the central axis of the beam 10 centimeters greater than the practical range of the electrons shall not exceed the values stated in Table 2. Linear interpolation shall be used for values not stated.

Table 2

Maximum Energy of Electron Beam in MeV	X-ray Absorbed Dose As a Fraction of Maximum Absorbed Dose
1	0.03
15	0.05
35	0.10
50	0.20

6.5.4.2 Compliance with 6.5.4 shall be determined using:

6.5.4.2.1 A measurement within a tissue equivalent phantom with the incident surface of the phantom at the normal treatment distance and normal to the central axis of the beam;

6.5.4.2.2 The largest field size available which does not exceed 15 centimeters by 15 centimeters; and

6.5.4.2.3 A phantom whose cross-sectional dimensions exceed the measurement radiation field by at least 5 centimeters and whose depth is sufficient to perform the required measurement.

6.5.4.3 The measured ionization at the surface relative to maximum ionization along the central axis shall not exceed the limits stated in Table 3. Linear interpolation shall be used for values not stated.

Table 3

Maximum Photon Energy in MeV	Measured Ionization at surface relative to Maximum Ionization along central axis
1	0.80
2	0.70
5	0.60
15	0.50
35	0.40
50	0.20

6.5.4.4 Compliance with 6.5.4.3 shall be determined by measurements made:

6.5.4.4.1 Within a tissue equivalent phantom using an instrument which will allow extrapolation to the surface absorbed dose;

6.5.4.4.2 Using a phantom whose size and placement meet the requirements of 6.5.4.2;

6.5.4.4.3 After removal of all beam modifying devices which can be removed without the use of tools, except for beam scattering or beam-flattening filters; and

6.5.4.4.4 Using the largest field size available which does not exceed 15 centimeters by 15 centimeters.

6.5.5 Beam Monitors. All therapy systems shall be provided with radiation detectors in the radiation head.

6.5.5.1 Equipment manufactured after January 1, 1994, shall be provided with at least two independent radiation detectors. The detectors shall be incorporated into two independent dose monitoring systems.

6.5.5.2 Equipment manufactured before January 1, 1994, shall be provided with at least one radiation detector. This detector shall be incorporated into a primary dose monitoring system.

6.5.5.3 The detector and the system into which that detector is incorporated shall meet the following requirements:

6.5.5.3.1 Each detector shall be removable only with tools and shall be interlocked to prevent incorrect positioning.

6.5.5.3.2 Each detector shall form part of a dose monitoring system from whose readings in dose monitor units the absorbed dose at a reference point in the treatment volume can be calculated.

6.5.5.3.3 Each dose monitoring system shall be capable of independently monitoring, interrupting, and terminating irradiation.

6.5.5.3.4 For new equipment, the design of the dose monitoring systems shall assure that: a) Malfunctioning of one system shall not affect the correct functioning of the secondary system; and b) Failure of any element common to both systems which could affect the correct function of both systems shall terminate irradiation.

6.5.5.3.5 Each dose monitoring system shall have a legible display at the treatment control panel. For new equipment, each display shall:

6.5.5.3.5.1 Maintain a reading until intentionally reset to zero;

6.5.5.3.5.2 Have only one scale and no scale multiplying factors for each mode of operation; and

6.5.5.3.5.3 Utilize a design such that increasing dose is displayed by increasing numbers and shall be so designed that, in the event of an overdosage of radiation, the absorbed dose may be accurately determined; and

6.5.5.3.6 In the event of power failure, the dose monitoring information required by 6.5.5.3.5 displayed at the control panel at the time of failure shall be retrievable in at least one system for a 20 minute period of time.

6.5.6 Beam Symmetry. In new equipment inherently capable of producing useful beams with unattenuated asymmetry exceeding 5 percent, the asymmetry of the radiation beam in two orthogonal directions shall be monitored before the beam passes through the beam-limiting device. Facilities shall be provided so that, if the difference in dose rate between one region and another region symmetrically displaced from the central axis of the beam exceeds 5 percent of the central axis dose rate, indication of this condition is made at the control panel; and if this difference exceeds 10 percent, the irradiation is terminated.

6.5.7 Selection and Display of Dose Monitor Units.

6.5.7.1 Irradiation shall not be possible until a selection of a number of dose monitor units has been made at the treatment control panel.

6.5.7.2 The preselected number of dose monitor units shall be displayed at the treatment control panel until reset manually for the next irradiation.

6.5.7.3 After termination of irradiation, it shall be necessary to manually reset the dosimeter display to zero before subsequent treatment can be initiated.

6.5.7.4 For new equipment, after termination of irradiation, it shall be necessary to manually reset the preselected dose monitor units before irradiation can be initiated.

6.5.8 Termination of Irradiation by the Dose Monitoring System or Systems during Stationary Beam Therapy.

6.5.8.1 Each primary system shall terminate irradiation when the preselected number of dose monitor units has been detected by the system.

6.5.8.2 If original design of the equipment included a secondary dose monitoring system, that system shall be capable of terminating irradiation when not more than 15 percent or 40 dose monitor units, whichever is smaller, above the preselected number of dose monitor units set at the control panel has been detected by the secondary dose monitoring system.

6.5.8.3 For equipment manufactured after January 1, 1994, a secondary dose monitoring system shall be present. That system shall be capable of terminating irradiation when not more than 10 percent or 25 dose monitoring units, whichever is smaller, above the preselected number of dose monitor units set at the control panel has been detected by the secondary dose monitoring system.

6.5.8.4 For equipment manufactured after January 1, 1994, an indicator on the control panel shall show which dose monitoring system has terminated irradiation.

6.5.9 Interruption Switches. It shall be possible to interrupt irradiation and equipment movements at any time from the operator's position at the treatment control panel. Following an interruption, it shall be possible to restart irradiation without any reselection of operating conditions. If any change is made of a preselected value during an interruption, irradiation and equipment movements shall be automatically terminated.

6.5.10 Termination Switches. It shall be possible to terminate irradiation and equipment movements or go from any interruption condition to termination conditions at any time from the operator's position at the treatment control panel.

6.5.11 Timer.

6.5.11.1 A timer which has a display shall be provided at the treatment control panel. The timer shall have a preset time selector and an elapsed time indicator.

6.5.11.2 The timer shall be a cumulative timer which activates with the production of radiation and retains its reading after irradiation is interrupted or terminated. After irradiation is terminated and before irradiation can be reinitiated, it shall be necessary to reset the elapsed time indicator to zero.

6.5.11.3 For equipment manufactured after the effective date of these regulations, after termination of irradiation and before irradiation can be reinitiated, it shall be necessary to manually reset the preset time selector.

6.5.11.4 The timer shall terminate irradiation when a preselected time has elapsed if the dose monitoring systems have not previously terminated irradiation.

6.5.12 Selection of Radiation Type. Equipment capable of both x-ray therapy and electron therapy shall meet the following additional requirements:

6.5.12.1 Irradiation shall not be possible until a selection of radiation type has been made at the treatment control panel.

6.5.12.2 An interlock system shall be provided to ensure that the equipment can emit only the radiation type which has been selected.

6.5.12.3 An interlock system shall be provided to prevent irradiation if any selected operations carried out in the treatment room do not agree with the selected operations at the treatment control panel.

6.5.12.4 An interlock system shall be provided to prevent irradiation with x-ray except to obtain a port film when electron applicators are fitted.

6.5.12.5 An interlock system shall be provided to prevent irradiation with electrons when accessories specific for x-ray therapy are fitted.

6.5.12.6 The radiation type selected shall be displayed at the treatment control panel before and during irradiation.

6.5.13 Selection of Energy. Equipment capable of generating radiation beams of different energies shall meet the following requirements:

6.5.13.1 Irradiation shall not be possible until a selection of energy has been made at the treatment control panel.

6.5.13.2 An interlock system shall be provided to prevent irradiation if any selected operations carried out in the treatment room do not agree with the selected operations carried out at the treatment control panel.

6.5.13.3 The nominal energy value selected shall be displayed at the treatment control panel before and during irradiation.

6.5.13.4 For new equipment, an interlock system utilizing monitoring of the bending magnet current shall be provided to terminate irradiation if the energy of the electrons striking the target or electron window deviates by more than 20 percent or 3 MeV, whichever is smaller, from the selected nominal energy.

6.5.14 Selection of Stationary Beam Therapy or Moving Beam Therapy. Equipment capable of both stationary beam therapy and moving beam therapy shall meet the following requirements:

6.5.14.1 Irradiation shall not be possible until a selection of stationary beam therapy or moving beam therapy has been made at the treatment control panel.

6.5.14.2 An interlock system shall be provided to ensure that the equipment can operate only in the mode which has been selected.

6.5.14.3 An interlock system shall be provided to prevent irradiation if any selected operations carried out in the treatment room do not agree with the selected operations carried out at the treatment control panel.

6.5.14.4 The mode of operation shall be displayed at the treatment control panel.

6.5.14.5 An interlock system shall be provided to terminate irradiation if movement of the gantry:

6.5.14.5.1 Occurs during stationary beam therapy; or

6.5.14.5.2 Stops during moving beam therapy unless such stoppage is a preplanned function..

6.5.14.6 Moving beam therapy shall be controlled to obtain the selected relationships between incremental dose monitor units and incremental angle of movement:

6.5.14.6.1 An interlock system shall be provided to terminate irradiation if the number of dose monitor units delivered in any 10 degrees of arc differs by more than 20 percent from the selected value.

6.5.14.6.2 Where gantry angle terminates the irradiation in arc therapy, the dose monitor units shall differ by less than 5 percent from the value calculated from the absorbed dose per unit angle relationship.

6.5.14.7 Where the dose monitor system terminates the irradiation in moving beam therapy, the termination of irradiation shall be as required in 6.5.8.

6.5.15 Absorbed Dose Rate. Asystem shall be provided from whose readings the absorbed dose rate at a reference point in the treatment volume can be calculated. The radiation detectors specified in 6.5.5 may form part of this system. In addition:

6.5.15.1 The dose monitor rate shall be displayed at the treatment control panel.

6.5.15.2 If the equipment can deliver under any conditions an absorbed dose rate at the normal treatment distance more than twice the maximum value specified by the manufacturer for any machine parameter utilized, a device shall be provided which terminates irradiation when the absorbed dose rate exceeds a value twice the specified maximum. The dose rate at which the irradiation will be terminated shall be in a record maintained by the registrant.

6.5.16 Location of Virtual Source and Beam Orientation. The registrant shall determine, or obtain from the manufacturer, the location with reference to an accessible point on the radiation head of:

6.5.16.1 The x-ray target or the virtual source of x-rays; and

6.5.16.2 The electron window or the virtual source of electrons if the system has electron beam capabilities.

6.5.17 System Checking. Capabilities shall be provided so that all radiation safety interlocks can be checked for operation.

6.5.18 Facility and Shielding Requirements. In addition to RHB 6.2 of these rules, the following design requirements shall apply:

6.5.18.1 Protective Barriers. All protective barriers shall be fixed except for entrance doors or beam interceptors.

6.5.18.2 Control Panel. The control panel shall be located outside the treatment room.

6.5.18.3 Viewing Systems.

6.5.18.3.1 Windows, mirrors, closed-circuit television, or an equivalent system shall be provided to permit continuous observation of the patient following positioning and during irradiation and shall be so located that the operator may observe the patient from the control panel.

6.5.18.3.2 When the primary viewing system is by electronic means, an alternate viewing system, which may be electronic, shall be available for use in the event of failure of the primary viewing system.

6.5.19 Aural Communications. Provision shall be made for continuous two-way aural communication between the patient and the operator at the control panel independent of the particle accelerator. However, where excessive noise levels or treatment requirements make aural communication impractical, other methods of communication shall be used. When this is the case, a description of the alternate method shall be submitted to, and approved by the Department.

6.5.20 Room Entrances. Treatment room entrances shall be provided with warning lights in readily observable positions near the outside of all accessible doors to indicate when the useful beam is "on" and "off".

6.5.21 Entrance Interlocks. Interlocks shall be provided such that all entrance doors must be closed before treatment can be initiated or continued. If the radiation beam is interrupted by any door opening, it shall not be possible to restore the machine to operation without closing the door and reinitiating irradiation by manual action at the control panel.

RHB 6.6 Operational Requirements for X-ray and Electron Therapy Systems with Energies of 1 MeV and Above.

6.6.1 Radiological Physics Support. The services of a radiological physicist shall be utilized in facilities having therapy systems with energies of 1 MeV and above. The radiological physicist shall be responsible for:

6.6.1.1 Calibration;

6.6.1.2 Supervision and review of patient dosimetry;

6.6.1.3 Beam data acquisition and storage for computer dosimetry, and supervision of its use;

6.6.1.4 Quality assurance, including spot check review; and

6.6.1.5 Consultation with the radiation therapist in treatment planning, as needed.

6.6.1.2 The radiological physicist described in 6.6.1 shall also be available and responsive to immediate problems or emergencies.

6.6.2 Surveys.

6.6.2.1 All new facilities, and existing facilities not previously surveyed, shall have a survey made by, or under the direction of, the radiological physicist. In addition, such surveys shall be done after any change in the facility or equipment which might cause a significant increase in radiation hazard.

6.6.2.2 The registrant shall obtain a written report of the survey and a copy of the report shall be transmitted by the registrant to the Department within 30 days of the first patient treatment following the survey.

6.6.2.3 The survey and report shall indicate all instances where the installation, in the opinion of the radiological physicist, is in violation of applicable rules or regulations.

6.6.3 Calibrations.

6.6.3.1 The calibration of systems subject to 6.5 shall be performed in accordance with an established calibration protocol acceptable to the Department before the system is first used for irradiation of a patient and thereafter at time intervals which do not exceed 12 months and after any change which might significantly alter the calibration, spatial distribution, or other characteristics of the therapy beam. The protocol used shall be a nationally accepted standard, such as one established by the American Association of Physicists in Medicine.

6.6.3.2 The calibration shall be performed by or under the direct supervision of the radiological physicist who is physically present at the facility during the calibration.

6.6.3.3 Calibration radiation measurements required by 6.6.3 shall be performed using a dosimetry system:

6.6.3.3.1 Having a calibration factor traceable to a national standard;

6.6.3.3.2 Which has been calibrated within the previous 2 years and after any servicing that may have affected its calibration;

6.6.3.3.3 Which has been calibrated in such a fashion that an uncertainty can be stated for the radiation quantities monitored by the system; and

6.6.3.3.4 Which has had constancy checks performed on the system as specified by the radiological physicist.

6.6.3.4 Calibrations shall be in sufficient detail that the dose at a reference point in tissue equivalent phantom may be calculated to within an uncertainty of 5 percent.

6.6.3.5 The calibration of the therapy unit shall include, but not be limited to, the following determinations:

6.6.3.5.1 Verification that the equipment is operating in compliance with the design specifications concerning the light localizer, all patient positioning lights, and back-pointer alignment with the isocenter when applicable, variation in the axis of rotation for the table, gantry, and collimator system, and beam flatness and symmetry at the specified depth.

6.6.3.5.2 The absorbed dose rate at various depths in a tissue equivalent phantom for the range of field sizes used, for each effective energy, that will verify the accuracy of the dosimetry of all therapy procedures utilized with that therapy beam.

6.6.3.5.3 The uniformity of the radiation field to include symmetry, flatness, and dependence on gantry angle.

6.6.3.5.4 Verification that existing isodose charts applicable to the specific machine continue to be valid or are updated to existing machine conditions.

6.6.3.5.5 Verification of transmission factors for all accessories such as wedges, shadow trays, and/or universal beam modifying devices.

6.6.3.6 Records of calibration measurements under 6.6.3.1 and dosimetry system calibrations under 6.6.3.3 shall be maintained for 5 years after completion of the full calibration.

6.6.3.7 A copy of the latest calibrated absorbed dose rate measured pursuant to 6.6.3.1 shall be available.

6.6.4 Spot Checks. Spot checks shall be performed on systems subject to RHB 6.5 during calibrations and at intervals established by the radiological physicist, not to exceed monthly, using a nationally accepted standard such as one established by the American College of Radiology, American Association of Physicists in Medicine, American College of Medical Physics, etc.

6.6.4.1 The spot check procedures shall be in writing and shall have been developed by the radiological physicist. A copy of the procedure shall be submitted to the Department upon request.

6.6.4.2 If a radiological physicist does not perform the spot check measurements, the results of the spot check measurements shall be reviewed by the radiological physicist within 7 treatment days.

6.6.4.3 The spot check procedures shall specify the frequency at which tests or measurements are to be performed and the acceptable tolerance for each parameter measured in the spot check when compared to the value for that parameter determined in the calibration.

6.6.4.4 Spot checks shall be made at a depth beyond the calibration depth but no deeper than the 80% ionization depth.

6.6.4.5 Where a system has built-in devices which provide a measurement of any parameter during irradiation, such measurement shall not be utilized as a spot check measurement.

6.6.4.6 A parameter exceeding a tolerance set by the radiological physicist shall be corrected before the system is used for patient irradiation.

6.6.4.7 Whenever a spot check indicates a significant change in the operating characteristics of a system, as specified in the radiological physicist's spot check procedures, the system shall be recalibrated, as required in 6.6.3.

6.6.4.8 Records of spot check measurements and any necessary corrective actions shall be maintained by the registrant for a period of 3 years after completion of the spot check measurements.

6.6.4.9 Whenever a spot check requires a radiation measurement, such measurement shall be obtained using a system satisfying the requirements of 6.6.3.3 or which has been intercompared with a system meeting those requirements within the previous year.

6.6.5 Prohibited Use. The system shall not be used in the administration of radiation therapy unless the requirements of RHB 6.6.1 through 6.6.4 have been met.

RHB 6.7 Misadministration Report Requirements of All Therapeutic X-ray Systems. All facilities utilizing therapeutic x-ray systems are subject to the misadministration reporting requirements in RHB 1.11.